

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

|                                   |                           |
|-----------------------------------|---------------------------|
| IN RE: DIET DRUGS (PHENTERMINE/ ) |                           |
| FENFLURAMINE/DEXFENFLURAMINE) )   | MDL NO. 1203              |
| PRODUCTS LIABILITY LITIGATION )   |                           |
| )                                 |                           |
| )                                 |                           |
| THIS DOCUMENT RELATES TO: )       |                           |
| )                                 |                           |
| SHEILA BROWN, et al. )            | CIVIL ACTION NO. 99-20593 |
| v. )                              |                           |
| )                                 |                           |
| AMERICAN HOME PRODUCTS )          | 2:16 MD 1203              |
| CORPORATION )                     |                           |

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**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.**

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Bartle, J.

July 19, 2011

Georgia J. Lang ("Ms. Lang" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Leo Lang, Ms. Lang's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Richard Callihan, M.D., F.A.C.C. Based on an echocardiogram dated August 1, 2002, Dr. Callihan attested in Part II of Ms. Lang's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Based on such findings,

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3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$496,153.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Marcus Brann, M.D., F.A.C.C., F.A.C.P., stated, "The mitral valve is anatomically normal but demonstrates moderate regurgitation." Dr. Brann, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Brann also stated that claimant had "mild left atrial enlargement." Specifically, Dr. Brann determined that Ms. Lang's left atrial dimension measured 65 mm in the left atrial supero-inferior systolic dimension and 41 mm in the left atrial antero-posterior systolic dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors needed to qualify for a Level II claim.

systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2) (b).

In August, 2006, the Trust forwarded the claim for review by Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists.<sup>5</sup> In audit, Dr. Yao concluded that there was no reasonable medical basis for Dr. Callihan's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation.

Dr. Yao explained:

[T]echnical setting incorrect. [N]yquist limit 51, later in [echocardiogram] study decreased to 46. [S]onographer incorrect tracing of mitral regurgitation - RJA; should not include trace of low velocity non regurgitant flow. 2+ [mitral regurgitation] seen in real time echocardiogram.

Dr. Yao also found that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal

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5. The Trust originally forwarded Ms. Lang's claim for review in or around March, 2004. The auditing cardiologist agreed with Dr. Callihan's Green Form representations, but the Trust later determined that the echocardiogram included inserted frames. Pursuant to Pretrial Order ("PTO") No. 5517 (July 27, 2005), claimant elected to have the inserted frames removed and the claim re-audited. Thus, in March, 2006, the Trust forwarded Ms. Lang's claim, including the redacted echocardiogram, for audit. Although the auditing cardiologist again agreed with Dr. Callihan's Green Form representations, the Trust submitted the claim for review by the Consensus Expert Panel ("CEP") pursuant to PTO No. 6100 (Mar. 31, 2006) (adopting Court Approved Procedure No. 11 ("CAP 11")). Based on the recommendation of the CEP, Ms. Lang's claim and redacted echocardiogram were submitted to another auditing cardiologist, Dr. Yao, for review. Dr. Yao's review is the subject of this show cause proceeding.

left atrial dimension, concluding that the "left atrial dimension [was] not increased." Specifically, Dr. Yao measured claimant's left atrial dimension as 52 mm in the left atrial supero-inferior systolic dimension and 39 mm in the left atrial antero-posterior systolic dimension.

Based on Dr. Yao's findings, the Trust issued a post-audit determination denying Ms. Lang's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant argued that there was a reasonable medical basis for her claim because, although the auditing cardiologist found mild mitral regurgitation, he observed that "2+ [mitral regurgitation was] seen in real time." Ms. Lang also asserted that she should prevail because the results of the Trust's re-audit of her claim pursuant to PTO No. 5517 were consistent with the results of the initial, favorable audit. According to claimant, the results of the audit by Dr. Yao should be "thrown out" because his review constituted an impermissible third audit.

The Trust then issued a final post-audit determination again denying Ms. Lang's claim. Claimant disputed this final

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Lang's claim.

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement.

See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Lang's claim should be paid. On January 22, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings.  
See PTO No. 6873 (Jan. 22, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 13, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Advisor Report are now before the court for final determination.

See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant states that she "disagrees with the medical findings of the Auditing Cardiologist and the Trust's characterization of those medical findings." In response, the Trust argues that claimant has not established a reasonable medical basis for her claim because she did not rebut Dr. Yao's specific findings that claimant's attesting physician relied on improper echocardiogram settings and included non-regurgitant flow in his measurement of claimant's level of mitral regurgitation. Finally, the Trust contends that the claim and

redacted echocardiogram were properly submitted for re-audit pursuant to CAP 11.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's findings of both moderate mitral regurgitation and an abnormal left atrial dimension. Specifically, Dr. Vigilante stated in reference to the level of claimant's mitral regurgitation that:

I was able to digitally trace and calculate the RJA and LAA in the apical two chamber view. Although there was increased color gain, the Nyquist limit was more appropriately set at 51 cm per second at a depth of 19 cm in the apical two chamber view. I was able to determine an accurate RJA in the mid portion of systole. The worst representative RJA in the apical two chamber view was 4.6 cm<sup>2</sup>. I determined that the LAA in this view was 20.2 cm<sup>2</sup>. Therefore, the worst representative RJA/LAA ratio in the apical two chamber view was 23%. This qualified for moderate mitral regurgitation.

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... [T]here is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiographic study of August 1, 2002 demonstrated moderate mitral regurgitation with comments as above.

With respect to claimant's left atrial dimension, Dr. Vigilante found that:

Visually, the left atrium appeared mildly dilated. I digitized the cardiac cycles in the parasternal long-axis and apical four chamber views in which the left atrium

appeared the largest. I measured the left atrium by electronic calipers. I determined that the left atrial antero-posterior diameter was 4.0 cm. This measurement was taken between the posterior root of the aorta and posterior left atrial wall at the level of the aortic valve. This line was perpendicular to the supero-inferior axis of the left atrium. The sonographer's largest left atrial diameter in the parasternal long-axis view was 4.14 cm. This was an inaccurate determination as this measurement was taken on a diagonal within the left atrium. I determined that the left atrium measured 5.5 cm in the supero-inferior dimension. This measurement was taken from the mitral annulus to the posterior left atrial wall. This measurement was perpendicular to the mitral annulus. I excluded pulmonary vein structures in this measurement. My LAA determination of 24.5 cm<sup>2</sup> in the apical four chamber view is also consistent with mild left atrial enlargement.

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... [T]here is a reasonable medical basis for the Attesting Physician's answer to Green Form Question F.5. That is, the echocardiographic study of August 1, 2002 demonstrated an abnormal left atrial dimension supero-inferior axis with comments as above.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. Both the attesting physician and the reviewing cardiologist found that claimant's echocardiogram demonstrated moderate mitral regurgitation and an abnormal left atrial dimension. The Trust, based on Dr. Yao's findings that the sonographer used an inappropriate Nyquist limit and included

trace low velocity and non-regurgitant flow, challenged the attesting physician's findings.

Dr. Vigilante reviewed the echocardiogram. Although he confirmed that the sonographer used an inappropriate Nyquist limit and included low velocity and non-regurgitant flow, Dr. Vigilante nevertheless determined that the echocardiogram demonstrated moderate mitral regurgitation and an abnormal left atrial dimension.<sup>8</sup> Specifically, Dr. Vigilante measured an RJA/LAA ratio of 23% and found that the left atrium "measured 5.5 cm in the supero-inferior dimension."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Dr. Callihan, Dr. Brann, and Dr. Vigilante each found that claimant's echocardiogram demonstrated an RJA/LAA ratio greater than 20%. Moreover, an abnormal left atrial dimension is present when the left atrial supero-inferior systolic dimension is greater than 5.3 cm in the apical four chamber view or the left atrial antero-posterior systolic dimension is greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Dr. Callihan, Dr. Brann, and Dr. Vigilante also each found that claimant's echocardiogram

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8. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

demonstrated a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. Thus, claimant has established that her echocardiogram demonstrates moderate mitral regurgitation and an abnormal left atrial dimension as defined by the Settlement Agreement.<sup>9</sup>

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and that she consequently is entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of Ms. Lang's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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9. Given our resolution, we need not address claimant's remaining arguments.